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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

AMGEN INC.,

Plaintiff,

v.

SANDOZ INC., et al.,

Defendants.

Civil Action No. 18-11026 (MAS)(DEA)
(consolidated)

Hon. Michael A. Shipp, U.S.D.J.
Hon. Douglas E. Arpert, U.S.M.J.

**AMGEN'S BENCH BRIEF IN SUPPORT OF ITS
OBJECTION TO THE ADMISSION OF DTX-321**

I. Introduction

During cross-examination of Amgen's expert Dr. Stephen Davies on June 23, 2021, Defendants sought to admit inadmissible hearsay via an internal Celgene document (DTX-321) without proper authentication. DTX-321 is an internal Celgene presentation titled "Discovery of Apremilast A Selective PDE-4 Inhibitor." As Defendants noted at trial, the author of DTX-321 is Dr. Hon-Wah Man, a former Celgene employee. Amgen objected to both the use of the document

with Dr. Davies as well as to its admission.¹ Defendants' counsel initially stated that he was only using the document to "show a couple of chemical formulas." Trial Tr. at 1402:19–20. Later, he countered that DTX-321 is an internal Celgene "document[] produced in the ordinary course of business," and that Defendants are permitted to confront experts with documents that challenge the expert's opinions. *Id.* at 1494:20–1495:22. Defendants are wrong, for multiple reasons. First, DTX-321 is hearsay and Defendants have presented no evidence that any exception to hearsay applies. Second, Defendants have failed to authenticate DTX-321. Alternatively, to the extent the Court is inclined to admit DTX-321, it should be admitted only for the limited purpose and extent it was actually used with Dr. Davies at trial—i.e., to the two pages (pages 1 and 8) shown to Dr. Davies to establish the chemical formulas for apremilast and its racemate.

II. Legal Summary

Parties cannot seek admission of any document through any expert under the auspices of "confronting the expert," as doing so would subvert the Rules of Evidence. At a minimum, documentary evidence must be authenticated; that is, the party seeking admission "must produce evidence sufficient to support a finding that the item [for which admission is sought] is what [the party] claims it is." FRE 901(a). Moreover, documents are out of court statements: when their admission is sought for the truth of the matter asserted, they are hearsay, and thus inadmissible, with limited exception. FRE 801-807.

One route available to Defendants to both authenticate DTX-321 and to establish an exception to hearsay—but which they failed to avail themselves of—is the so-called "business

¹ Amgen also objected to a second document Defendants sought to admit via Dr. Davies, DTX-384 (the "Orange Book"). Upon further review, Amgen understands that DTX-384 has already been admitted. While Amgen maintains that this document is inappropriate to be admitted through Dr. Davies, because it has already been admitted, Amgen's argument has been mooted.

records exception.” That exception applies to a record of an act, event, condition, opinion, or diagnosis if: (a) the record was made at or near the time by, or from information transmitted by, someone with knowledge; (b) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling; (c) making the record was a regular practice of that activity; (d) these first three requirements are established by testimony or certification of the custodian or another qualified person; and (e) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness. FRE 803(6); FRE 902(11) (allowing only certification to satisfy (d) for authentication); *Wonderland Nurserygoods Co. Ltd. v. Thorley Indus. LLC*, 2014 WL 695549, at *12–14 (W.D. Pa. Feb. 24, 2014) (explaining and applying both rules, and citing string of Third Circuit decisions in support).

Evidence also need not be admitted wholesale, but can be admitted for a limited purpose.

See FRE 105.

III. Analysis

DTX-321 should not be admitted wholesale because it is inadmissible hearsay that Defendants have also failed to authenticate. If the Court is nevertheless inclined to admit DTX-321, such admission should be limited to the two pages Defendants showed to Dr. Davies—pages 1 and 8—and the testimony elicited regarding those pages.²

² It was not only improper, but wholly unnecessary, for Defendants to seek to establish the chemical formula of apremilast and its racemate by reviewing DTX-321 with Dr. Davies. Dr. Davies explicitly considered documents containing those same formulas in forming his opinions in this case. *E.g.*, JTX-156 at 6; DTX-556 at 2 (Davis Rebuttal Rpt. Materials Considered). If Defendants’ goal was simply to establish the chemical formulas of those molecules, they had no reason to use DTX-321. Thus, contrary to their representation to the Court, it is clear that Defendants intend to rely on DTX-321 for a purpose *other* than identifying the chemical formulas they presented to Dr. Davies. Given that the author of DTX-321 is Dr. Man, and none of the individuals on Defendants’ witness list could have authenticated DTX-321,

First, DTX-321 is inadmissible hearsay. Defendants clearly agree that the document is hearsay, as their only defense to Amgen's objection was that *Celgene* produced the document; i.e. that DTX-321 is *admissible* hearsay. Contrary to their assertions, however, Defendants have presented no evidence that establishes that this document was a *business record* of Celgene's. FRE 803(6). But, perhaps most fatal to their attempt to "back-door" admit this document through an expert,³ Defendants presented no testimony or certification from the custodian or other sufficiently qualified witness regarding DTX-321 or any of the first three requirements of the business records exception.

To satisfy the business records exception, the proffered witness or certifier must have personal familiarity with or at least personal understanding of the record-keeping system at issue such that they can lay the necessary foundation (i.e. items (a) through (c)). *Wonderland Nurserygoods*, 2014 WL 695549, at *12 (quoting and citing string of Third Circuit decisions). Dr. Davies was asked nothing about his understanding (to the extent he has any) of Celgene's

Defendants' request for admission of DTX-321 via Dr. Davies is a back-door attempt to introduce a document they intended to present to Dr. Man as part of their affirmative case. The Court has already affirmed that Defendants' failure to include Dr. Man on their witness list precludes them from soliciting Dr. Man's testimony. *See* Trial Tr. at 1290:16–1291:14. Defendants should not now be allowed to abrogate the Court's ruling by admitting DTX-321 through a witness who cannot provide the necessary authentication or foundation for a hearsay exception.

³ Experts may rely on hearsay; however, that does not make the underlying document itself admissible for its substance. FRE 703; *see also* 2 McCormick on Evidence § 324.3 n.6 (8th ed., Jan. 2020 update) ("No reported case has explicitly admitted evidence substantively under this provision."). Moreover, if such facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the factfinder *only if* their probative value in helping the factfinder evaluate the opinion substantially outweighs their prejudicial effect. FRE 703; *see also* 2 McCormick on Evidence § 324.3 (8th ed., Jan. 2020 update).

Although Dr. Davies was shown DTX-321 at deposition, Dr. Davies never relied on DTX-321 in forming his opinions in this case (it is not cited in his Materials Considered), nor have Defendants (to the extent they could) established that Dr. Davies had previously seen this document before his deposition or made any showing that DTX-321 is the type of evidence typically employed by experts in this field, a requirement of any such reliance. *See In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 748 (3d Cir. 1994).

business practices related to DTX-321. Thus, his testimony simply cannot satisfy Defendants burden. *Shu-Hui Chen v. Bouchard*, 347 F.3d 1299, 1308 n.2 (Fed. Cir. 2003) (upholding conclusion that documents “did not fall under the purview of” FRE 803(6) “[b]ecause [plaintiff] presented no testimony from the ‘custodian or other qualified witness’ that [said documents] were ‘records of regularly conducted activity,’ relying instead only on [plaintiff’s own] uncorroborated testimony”); *Wonderland Nurserygoods*, 2014 WL 695549, at *12–14 (denying admission of document under both FRE 803(6) and for lack of authentication because proffering party failed to offer custodian, qualified witness, or sufficient certification); *see also id.* (noting that, under Third Circuit precedent, “Rule 803(6) requires more than just ‘any fact witness’ to establish that [documents] are ‘records of regularly conducted activity’” (citing *Shu-Hui Chen*, 347 F.3d at 1308)).

For the same reasons, DTX-321 also lacks authentication. FRE 901, 902. Defendants have provided no certification related to DTX-321 to authenticate it as a domestic business record. FRE 902(11); *see also Wonderland Nurserygoods*, 2014 WL 695549, at *12–14. Moreover, Dr. Davies was asked only about two of its thirty-three pages.

Nevertheless, to the extent the Court is inclined to admit DTX-321, it should only do so for the limited purpose it was employed by Defendants with Dr. Davies pursuant to Rule 105. *See United States v. DeMauro*, 2021 WL 1979484, at *1, 6 (May 18, 2021 D.N.H.) (acknowledging that FRE 105 may be used to limit evidence in bench trial). Defendants stated to the Court that they only sought to use DTX-321 with Dr. Davies for the limited purpose of showing him a few chemical formulas contained therein. Trial Tr. at 1402:19–20. Counsel then elicited testimony from Dr. Davies regarding only pages 1 (the title page) and 8 in Dr. Man’s 33-page presentation, specifically about two chemical formulas on page 8—the formulas for apremilast and the racemate

Example 12 of the '358 Patent. *See id.* at 1403:13–1404:22. Given Dr. Davies' lack of testimony related to any other aspect or page of DTX-321, and in light of Defendants' representations to the Court regarding their purpose in using the document with Dr. Davies, only pages 1 and 8 of DTX-321 should—if any—be admitted for the limited purpose of establishing the facts to which Dr. Davies testified: the chemical formulas of apremilast and Example 12.

IV. Conclusion

In light of the foregoing, the Court should sustain Amgen's objection and bar Defendants from admitting DTX-321 into evidence. If the Court is inclined to admit DTX-321, it should only be admitted to establish the chemical formulas of apremilast and the Example 12 racemate of the '358 Patent.

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Respectfully submitted,

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